Richard Denison
<rdenison@environmentaldefense.org>
07/19/2006 06:54 PM

To: ChemRTK HPV@EPA, Rtk Chem@EPA, Karen Boswell/DC/USEPA/US@EPA, hjtroch@comcast.net
cc: Skip Matthews <mtc@mchsi.com>, Karen Florini <KFlorini@environmentaldefense.org>, Richard Denison <rdenison@environmentaldefense.org>
bcc:
Subject: Environmental Defense comments on Cyclohexanone Oxime (CAS# 100-64-l)

(Submitted via Internet 7/19/06 to boswell.karen@epa.gov, and hjtroch@comcast.net)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for **Cyclohexanone Oxime (CAS# 100-64-l).**

DSM Chemicals North America, Inc., in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted a test plan and robust summaries for cyclohexanone oxime.

Our review of this submission indicates that the test plan is carefully written and supported by numerous peer-reviewed references. The test plan also contains appendices to support the classification of this chemical as a closed-system intermediate, which include a description of its production and use. We defer to EPA as to whether this chemical qualifies for closed-system intermediate status.

Available data described address most required SIDS elements and are, for the most part, drawn from relatively recent studies. SIDS elements not addressed are those concerning the fate of cyclohexanone oxime in the environment, toxicity to invertebrates and algae and reproductive/developmental toxicity. A study to determine the developmental toxicity of cyclohexanone oxime is proposed. It is argued that, since cyclohexanone oxime is a closed-system intermediate, additional studies to address its fate in the environment, toxicity to invertebrates and algae and reproductive toxicity are unnecessary. Of the missing data elements, however, only reproductive toxicity need not be determined for closed-system intermediates; the other elements are required under the Challenge, and are important elements in understanding the potential for environmental effects, for example in the event of accidental releases.

While we defer to EPA on the closed-system intermediate question, we note several statements made that call into question whether this chemical is exclusively used as an intermediate. Specifically, we are concerned by use of the following words or phrases used in the test plan and/or robust summary:

- cyclohexanone oxime is used **"primarily as a captive intermediate"** in the production of caprolactam.

- **"most"** of the cyclohexanone oxime is used in the production of caprolactam
- **"our production methods are similar to those of other producers"**

These phrases suggest that something less than 100% of the cyclohexanone oxime produced by DSM Chemicals is used as a closed-system intermediate in the production of caprolactam. From the information provided, the reader has no way of knowing if other uses, not involving closed systems, are significant. Information regarding the percentage of total production used in the synthesis of caprolactam and other possible uses of cyclohexanone oxime should be included in the test plan. Also, we have no way of knowing if other producers of cyclohexanone oxime provide it for purposes not exclusively involving closed systems. Discussion of other producers and uses of this chemical should be provided in the test plan as well.

Cyclohexanone oxime has significant toxicity to mammals on repeated exposure to very low doses. Its environmental toxicity may also be quite significant. Thus, the lack of data regarding the fate of this chemical in the environment and its environmental toxicity need to be addressed and make information regarding all of the uses of this chemical vital to any assessment of risks associated with its production and use. This information should be provided to the satisfaction of the EPA prior to consideration of cyclohexanone oxime as a closed-system intermediate.

In summary, this is a relatively thorough and carefully prepared submission. However, we are not convinced by the information provided regarding the production and use of cyclohexanone oxime that it qualifies as a closed-system intermediate. Therefore, we recommend that the EPA request and review additional information concerning the production and use of cyclohexanone oxime prior to approval of this for submission in response to the HPV Challenge. If EPA is satisfied that cyclohexanone oxime is indeed a closed-system intermediate, then provision of the additional data on environmental fate and toxicity to invertebrates and algae would make this an acceptable submission. If not, additional studies of reproductive toxicity are also needed.

Thank you for this opportunity to comment.

Hazel B. Matthews, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense